

REMARKS

Claims 1-20 were pending in the application. New claims 21-27 have been added, support for which can be found throughout the application as originally filed and at, for example, Examples 5-10 of the originally filed application. Table 1 on pages 81-82 teaches antisense oligonucleotides that inhibit the expression of Toll-like receptor 4 by at least 50% (claim 26) or 70% (claim 27). No new matter has been added. Upon entry of this amendment, claims 1-27 will be pending.

The Communication dated October 1, 2003 asserts that Applicants response filed July 7, 2003 was not fully responsive because it allegedly failed to elect an invention. Applicants disagree. **The response filed July 7, 2003 clearly indicated that Applicants elected the claims of Group I (claims 1-14) and SEQ ID NO:25, with traverse.** Applicants additionally urged the Examiner to treat the second election of invention (for which Applicants elected SEQ ID NO:25) as a species election rather than an additional election of invention. Applicants' position is fully supported by the MPEP as described below (as originally recited in the response dated July 7, 2003). Applicants respectfully request the Examiner to address Applicants' request for an election of species.

The Examiner required Applicants to elect one of two groups, and also to elect up to one of the sequences set forth in claim 3 alleging that the sequences are unrelated. The Office further alleges that a search of all of the sequences set forth in claim 3 would present an undue burden on the Patent and Trademark Office. Applicants respectfully traverse and request reconsideration of the Restriction Requirement.

Applicants provisionally elect the claim of Group I (claims 1-14) and provisionally elect SEQ ID NO:25 for examination. Notwithstanding the foregoing, however, as discussed below, Applicants respectfully point out that any restriction requirement of claim 3 should be a *species* election.

The procedure for handling applications that include generic claims is set forth in 37 CFR § 1.146. This rule provides that:

[I]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a

species of his or her invention to which his or her claim will be restricted *if no claim to the genus is found to be allowable*.

As stated in MPEP § 809.02(a), “upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141.” Where generic claims are present, an applicant *may* be required to elect a *species* for initial examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable.

MPEP § 806.04(b) states that species may be related inventions. Specifically this section of the MPEP directs that:

[w]here inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction *must* be determined by both the practice applicable to election of species and the practice applicable to other types of restriction such as those covered in MPEP § 806.05- § 806.05(i). If restriction is improper under either practice, it should not be required.


The species set forth in claim 3 (particular oligonucleotide sequences) fall within the genus of claim 1 (compounds targeted to a nucleic acid encoding toll-like receptor 4) and the subgenus of claim 2 (antisense oligonucleotide compounds targeted to a nucleic acid encoding toll-like receptor 4). The species are also related; each species is a compound which both targets and inhibits the expression of toll-like receptor 4. Taking the Examiner’s comments that each sequence is distinct because they have different nucleotide sequence would result in the untenable conclusion that there is no such thing as related sequences or species. Furthermore, each sequence recited in claim 3 hybridizes to the **same** mRNA and has the **same** function—inhibit the expression of toll-like receptor 4. Therefore, as described above, “the question of restriction *must* be determined by both the practice applicable to election of species and the practice applicable to other types of restriction such as those covered in MPEP § 806.05- § 806.05(i).” In the present case, restriction must be determined by the practice applicable to election of species. The practice applicable to the types of restriction such as those covered in MPEP § 806.05- § 806.05(i) is clearly not relevant to the present invention; these sections of the MPEP discuss related inventions, including “Combination and Subcombination or Element”, “Old Combination

– Novel Subcombination”, “Criteria of Distinctness for Combination, Subcombination, or Element of a Combination”, “Subcombinations Usable Together”, “Process and Apparatus for Its Practice – Distinctness”, “Process of Making and Product Made – Distinctness”, “Apparatus and Product Made – Distinctness”, “Product and Process of Using”, and “Product, Process of Making, and Process of Using – Product Claim Not Allowable.”

As MPEP § 806.04(b) states that species that are related inventions *must* be determined by both the practice applicable to election of species and the practice applicable to other types of restriction such as those covered in MPEP § 806.05- § 806.05(i) and the rules detailed by MPEP § 806.05- § 806.05(i) are not relevant to the present invention, Applicants proceed under the assumption that the Office has levied an election of species requirement against pending claim 3.

The examination of the pending claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6914 to clarify any unresolved issues raised by this response. In addition, Applicants filed a Power of Attorney with Revocation and Change in Correspondence Address on September 18, 2003. Accordingly, please address all future correspondence to the address listed below (which is associated with Customer Number 34138).

Respectfully submitted,



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